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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,037	04/20/2001	Gordon J. Dow	PU3556USW	9461

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DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY  
GLAXOSMITHKLINE  
FIVE MOORE DR., PO BOX 13398  
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER
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HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617  
DATE MAILED: 09/08/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/830,037	DOW ET AL.
	Examiner	Art Unit
	San-ming Hui	1617

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 June 2003.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-13, 19, 21-23 and 25-27 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-13, 19, 21-23 and 25-27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

The petition of reviving the application is grant on June 27, 2003.

Applicant's amendments filed June 16, 2003 have been entered.

The cancellation of claims 14-18, 20, and 24 and the addition of claims 25-27 in amendments filed June 16, 2003 are acknowledged.

The outstanding rejections under 35 USC 112, second paragraph are withdrawn in view of the amendments filed June 16, 2003.

Claims 1-13, 19, 21-23, and 25-27 are pending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 19, 21-23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (WO 92/14472 from the Information Disclosure Statement received April 20, 2001) and Gordon (Clinical therapeutics, 1998; 20(1): 26-39) in view of Richards (US Patent 4,985,418), references of record in the previous office action mailed July 18, 2001, and Budavari (Merck Index 11<sup>th</sup> ed. 1989, monograph 6021 and 7879).

Hill teaches a topical composition employing 0.05% of the corticosteroid, fluticasone propionate, 10.00% of cetostearyl alcohol, 10% of White Soft Paraffin,

2.50% of Polysorbate 60, 10.00% of propylene glycol, and purified water (see particularly Example 1). Hill also teaches that the topical composition is prepared by mixing the ingredients and melting the mixture and then cool the mixture down (See particularly page 2, third paragraph). Hill also teaches that the topical composition is useful in treating skin conditions including inflammation (See particularly page 1, 6<sup>th</sup> paragraph).

Gordon teaches a corticosteroid (clobetasol) containing composition, free of mineral oil and white soft paraffin, employing Cetostearyl alcohol, cetomacrogol 1000, Isopropyl myristate, propylene glycol, Dimethicone 360, citric acid, sodium citrate, imidurea, and water (see page 28, table 1). Gordon also teaches the function for adding occlusive agents in emollient cream will help moistening the skin (See page 32, col. 2). Gordon also teaches the absorption of the steroids is greater when more occlusive agents are present in the formulation (See page 32, col. 2).

The references do not expressly teach the composition as up to 5% of mineral oil and white soft paraffin. The references do not expressly teach the employment of methyl paraben and propyl paraben in the lotion. The references do not expressly teach the preparation of the topical composition employing these steps of mixing the ingredients at an elevated temperature and then heating the mixture. The references do not expressly teach the viscosity of the topical compositions to be 2,000 to 17,000 cps or 3000 to 13,000 cps. Both references do not expressly teach the blanching score of the lotion. The references do not expressly teach the weight percentage of mineral oil or white soft paraffin to be about 2.0 to 5.0%.

Richards teaches that methyl paraben and propyl paraben are excipients known to be useful in a fluticasone topical composition (See particular col. 5, lines 20-30). Richards also teaches the preparation of the fluticasone composition involving the process of mixing the ingredients at 70 degree Celsius and then heating the mixture to 70 degree (See particular col. 6, line 10-17).

Budavari teaches both methyl paraben and propyl paraben are useful as preservatives and pharmaceutic aids (See the Use section of the monographs).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to formulate a topical fluticasone composition as up to 5% of mineral oil and white soft paraffin with the ingredients herein in the amount herein. It would have also been obvious for one of ordinary skill in the art at the time the invention was made to prepare a topical fluticasone composition that has the viscosity herein and the blanching score herein. It would have also been obvious for one of ordinary skill in the art at the time the invention was made to prepare a topical fluticasone composition by mixing the ingredients at an elevated temperature and then heating up the mixture.

One of ordinary skill in the art would have been motivated to formulate a topical fluticasone composition, as free of mineral oil and white soft paraffin, with the excipient ingredients in the amount herein. Possessing the teachings of the cited prior art, one of ordinary skill in the art would be reasonably expected to successfully substitute clobetasol with fluticasone to formulate an emollient cream as up to 5% of mineral oil and white soft paraffin. Furthermore, the excipients herein are known to be useful in formulating topical corticosteroid compositions. Therefore, incorporating all the

excipients herein with any known active corticosteroid compounds including fluticasone would have been reasonably expected to be useful in preparing the topical fluticasone composition herein. Furthermore, the optimization of desired effect parameters (amount of excipients) is obvious as being within the skill of the artisan, absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to prepare a topical fluticasone composition that has the viscosity herein and the blanching score herein because the optimization of effect parameters (e.g., viscosity and blanching score) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Based on Richards, heating and mixing those ingredients herein recited in the method of preparing the topical fluticasone composition is obvious, absent evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments filed June 16, 2003 averring the cited prior art's failure to provide motivation to select the specific excipients have been fully considered but they are not persuasive. Gordon provides the motivation of adding or adjusting the amount of the occlusive agents since it can affect the absorption of the steroid, and thus, its efficacy in the skin (i.e., affecting blanching scores).

Applicant's arguments filed June 16, 2003 averring the cited prior art's failure to provide motivation to adjust the amount of excipients have been fully considered but they are not persuasive. Optimization of effect parameters (e.g., amount of excipients)

is obvious as being within the skill of the artisan, absent evidence to the contrary. Examiner notes that adjusting various amounts of excipient would sometimes change the physical properties of the composition (e.g., viscosity alters as a result of increase or decrease the thickening or suspending agents). Such adjust is considered as obvious as being within the purview of skilled artisan.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
San-ming Hui  
Patent Examiner  
Art Unit 1617